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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/821,256	04/08/2004	Robbert Benner	3077-6420US	1851

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EXAMINER	
KIM, YUNSOO	

ART UNIT	PAPER NUMBER
1644	

DATE MAILED: 03/02/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/821,256	BENNER ET AL.	
	Examiner	Art Unit	
	Yunsoo Kim	1644	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on *09 December 2005*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-13* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-13* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *4/13/04, 5/13/04,* & 9/28/05 ~~42~~
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

1. Claims 1-13 are pending.

2. Applicants' election without traverse of Group I, drawn to claims 1-13 reads on elected species of SEQ ID NO:2 in the reply filed on 12/9/05 is acknowledged.

3. Applicants' IDS filed on 4/8/04, 5/13/04 and 9/28/05 have been acknowledged.

Some duplicates on 5/13/04 have been crossed out and PCT search report on 9/28/05 has been considered but crossed out as being inappropriate for IDS. In addition, the foreign documents listed on IDS filed 4/8/04, 2706772, DE 3715662 and DE 19953339 have been considered to the extent to the abstract. Applicant is invited to submit English translation for the further consideration of said documents.

4. The specification is objected to as failing to provide proper antecedent basis for the claimed subject matter. See 37 CFR 1.75(d)(1) and MPEP § 608.01(o). Correction of the following is required: The term "orally" in claim 5 does not have the written support in the specification. Applicant is requested to identify the written support for the claimed limitation.

5. Non-initialed and/or non-dated alterations have been made to the oath or declaration. See 37 CFR 1.52(c).

6. 35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

7. Claims 1-13 are provisionally rejected under 35 U.S.C. 101 as claiming the same invention as that of claims 1-13 of copending Application No. 11/249,541. This is a provisional double patenting rejection since the conflicting claims have not in fact been patented.

8. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out this invention.

9. Claims 1-13 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a composition comprising of oligopeptides consisting of QGV or SEQ ID NO:2, does not reasonably provide enablement for a composition comprising any oligopeptide comprising QGV. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use of the invention commensurate in scope with these claims.

Factors to be considered in determining whether undue experimentation is required to practice the claimed invention are summarized *In re Wands* (858 F2d 731, 737, 8 USPQ2d 1400, 1404 (Fed.Cir.1988)). The factors most relevant to this rejection are the scope of the claim, the amount of direction or guidance provided, the lack of sufficient working examples, the unpredictability in the art and the amount of experimentation required to enable one of the skilled in the art to practice the claimed invention.

Having "comprising" considered open, the claims expand the oligopeptide of QGV to include additional non-disclosed amino acids. The specification does not provide sufficient guidance as to which amino acid sequence within the polypeptide can be unique and retain a distinct functional capability of reducing the blood urea nitrogen concentration.

Minor structural differences among structurally related compounds or compositions can result in substantially different or deleterious biological activities. Ngo *et al* teach that the amino acid positions within the polypeptide/protein that can tolerate change such as conservative substitution or no substitution, addition or deletion which are critical to maintain the protein's structure will require guidance (see Ngo et al., 1994, The Protein Folding Problem and Tertiary Structure Prediction, pp. 492-495 in particular).

Thus, Applicant has not provided sufficient guidance to enable one skill in the art to use claimed composition in manner reasonably correlated with the scope of the claims. The scope of the claims must bear a reasonable correlation with the scope of enablement. *In re Fisher*, 166 USPQ 18(CCPA 1970) indicates that the more unpredictable an area is, the more specific enablement is necessary in order to satisfy the statute.

In view of the quantity of experimentation necessary, the unpredictability of the art, the lack of sufficient guidance in the specification, the limited working examples, and the limited amount of direction provided given the breadth of the claims, it would take undue trials and errors to practice the claimed invention.

10. Claims 1-13 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Applicant is in possession of a composition comprising of oligopeptides consisting of SEQ ID NO:2 or QGV; however, applicant is not in possession of a composition comprising any oligopeptide comprising QGV. Consequently, conception in either case cannot be achieved until a representative description of the structural and functional properties of the claimed invention has occurred, regardless of the complexity or simplicity of the method. Adequate written description requires more than a mere statement that it is part of the invention. See Fiers v. Revel, 25 USPQ2d 1601, 1606 (CAFC 1993).

Vas-Cath Inc. v. Mahurkar, 19 USPQ2d 1111, makes clear that "applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession of the invention. The invention is, for purposes of the written description inquiry, whatever is now claimed." (See page 1117.) The specification does not "clearly allow persons of ordinary skill in the art to recognize that [he or she] invented what is claimed." (See Vas-Cath at page 1116). Consequently, Applicant was not in possession of the instant claimed invention. See University of California v. Eli Lilly and Co. 43 USPQ2d 1398.

Applicant is directed to the Revised Interim Guidelines for the Examination of Patent Applications Under the 35 U.S.C. 112, ¶ 1 "Written Description" Requirement, Federal Register, Vol. 66, No. 4, pages 1099-1111, Friday January 5, 2001.

11. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

12. Claims 1-4, 6, 7, 9-13 are rejected under 35 U.S.C. 102(b) as being anticipated by WO 01/72831 (IDS reference) as evidenced by Merck Index (17th ed. 1999, p. 1145-1146, 1841-1848, 2539, 2550).

The '831 publication teaches a method of treating septic shock by administration of synthetic immunoregulator NMPF (e.g. AQGV) in a patient (p 3-4, 18, 22, 27, 44, 55, 61, claims 3, 13, 22-25). The '831 publication further teaches the administration of the immunoregulator intraperitoneally in PBS (p. 39). As cardiac ischemia reperfusion was performed in coronary artery occlusion model (p. 53, 66), renal ischemia reperfusion test is included for diagnostic process for renal failure.

As is evidenced in Merck Index, p. 1145-46, septic shock causes acute renal failure and the blood urea concentration is increased as result of renal failure. Treating septic shock results lowering blood urea nitrogen concentration. Furthermore, the Merck Index teaches major causes for acute renal failure being septic shock (p. 1842, table), patient with oliguria has increased blood urea nitrogen in serum (p. 1145, 1847, table), decreased secretion of urine compared to 1-2.4L/day comparable to less than 0.5ml/kg/hr (p. 1145, 1842), increased potassium (p. 2539, in normal being 3.5 -5.3mmol/L) and maintain at 6 mmol/L (p. 1845) as indication, symptoms and signs of renal failure.

Reducing blood urea nitrogen concentration is inherent property of the oligopeptide composition consisting of SEQ ID NO:2. Thus, reference teachings anticipate the claimed invention.

13. Claims 1-5, 7-13 are rejected under 35 U.S.C. 102(e) as being anticipated by 2004/0013661 (IDS reference) as evidenced by Merck Index (17^{th} ed. 1999, p. 1145-1146, 1841-1848, 2539, 2550) and Merriam Webster's Dictionary (p. 82).

The '661 publication teaches a method of treating sepsis including bacterial infection (e.g. septic shock) or ischemia reperfusion injury by administration of pharmaceutical composition comprising synthetic immunoregulator AQGV in bolus (e.g. orally) or infusion (parenterally) with dose of 1-5 mg/kg bodyweight (abstract, claim 1, [0021-23], [0043-45], [0050]).

The '661 publication further teaches use of combination of immunoregulator ([0048]), use of diagnostic process to determine disease stage (claim 1) and septic shock causes multiple organ failure (e.g. renal failure, [0021]).

As is evidenced in Merck Index, p. 1145-46, septic shock causes acute renal failure and the blood urea concentration is increased as result of renal failure. Treating septic shock results lowering blood urea nitrogen concentration. Furthermore, the Merck Index teaches major causes for acute renal failure being septic shock (p. 1842, table), patient with oliguria has increased blood urea nitrogen in serum (p. 1145, 1847, table), decreased secretion of urine compared to 1-2.4L/day comparable to less than 0.5ml/kg/hr (p. 1145, 1842), increased potassium (p. 2539, in normal being 3.5 -5.3mmol/L) and maintain at 6 mmol/L (p. 1845) as indication, symptoms and signs of renal failure.

"Bolus" is defined in Merriam-Webster's Medical Desk Dictionary as a rounded mass, soft mass of chewed food, thus it is extended to include oral administration.

Reducing blood urea nitrogen concentration is inherent property of the oligopeptide composition consisting of SEQ ID NO:2. Thus, reference teachings anticipate the claimed invention.

14. No claims are allowable.

15. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Yunsoo Kim whose telephone number is 571-272-3176. The examiner can normally be reached on Monday thru Friday 8:30 - 5:00PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on 571-272-0841. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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February 23, 2006

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